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Office of Regulatory Policy Food and Drug Administration 10903 New Hampshire Ave., Bldg. 51, Rm. 6222 Silver Spring, MD 20993-0002

Attention: Beverly Friedman

The attached documents relate to the patent term extension application for U.S. Patent No. 6,204,257, which was filed on February 6, 2009, under 35 U.S.C. § 156.

Applicant is fulfilling their duty of disclosure pursuant to 37 C.F.R. § 1.765 by submitting information to the USPTO and FDA indicating that more than one application for patent term extension was filed for the single regulatory review period for the human drug product, LUSEDRATM, NDA No. 02-2244.

Inquiries regarding this communication should be directed to the undersigned at (571) 272-7755 (telephone) or (571) 273-7755 (facsimile).

Mary C. Till Legal Advisor

Office of Patent Legal Administration Office of the Deputy Commissioner for Patent Examination Policy

cc: Chr

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